1 QUALITY ASSURANCE PROGRAM

The Forensic Biology quality system is directed by the Commonwealth of Virginia Department of Criminal Justice Services Division of Forensic Science Quality Manual, hereinafter referenced as the Quality Manual.

1.1. GOALS AND OBJECTIVES

1.1.1 Goals

1.1.1.1 To support criminal justice agencies in the Commonwealth with DNA typing of selected biological materials associated with criminal investigations using polymerase chain reaction (PCR) based testing.

1.1.1.2 To maintain a DNA Data Bank of convicted offenders and arrestees.

1.1.1.3 To ensure the quality, integrity, and accuracy of the DNA typing data through the implementation of a detailed quality control program.

1.1.2 Objectives

1.1.2.1 Establish and monitor quality requirements for reagents, supplies, equipment, and analytical procedures.

1.1.2.2 Ensure that the entire DNA typing procedure is operating within the established performance criteria and that the quality and validity of the analytical data is maintained.

1.1.2.3 Ensure that problems are noted and that corrective action is taken and documented.

1.2 ORGANIZATION AND MANAGEMENT STRUCTURE

The organization and management of the Virginia Division of Forensic Science is addressed in the Quality Manual, Section 3, Organization and Management.

The management structure for the Virginia Division of Forensic Science is set forth in the Department of Criminal Justice Services, Division of Forensic Science Organizational Chart.

1.3 PERSONNEL QUALIFICATIONS AND TRAINING

The procedure for the qualification and training of personnel is addressed in the Quality Manual, Section 15, Personnel and Training.

The policy that addresses attending meetings and seminars is addressed in the Quality Manual, Section 15.8, Continuing Education and Training.

Training reports, transcripts, and position descriptions for all Forensic Biology personnel conducting DNA casework or Data Bank analyses are maintained by the Forensic Biology Program Manager, Section Chief, and/or the Section Supervisor.

1.4 FACILITIES

The Facilities of the Virginia Division of Forensic Science is addressed in the Quality Manual, Section 16, Facilities and Security.

1.5 EVIDENCE CONTROL

The procedure for the assignment of laboratory numbers to submission of physical evidence, and item [sub-item] numbers to evidence contained in the submission of physical evidence is addressed in the Quality Manual, Section 13, Case Files and File Administration.

The procedure for the handling of physical evidence is addressed in the Quality Manual, Section 20, Evidence Handling.

1.6 VALIDATION

The validation of new DNA technologies/methodologies utilized by the Virginia Division of Forensic Science, Forensic Biology Section is addressed in the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Procedure Manual, Section VI, Quality Assurance Program DNA Typing of Biological Materials. In addition, a summary of each validation study is maintained with the data. The summary and data are maintained by the Section Chief of the Forensic Biology Section as directed by Section 17 of the Quality Manual, Technical Procedures and Manuals.

1.7 ANALYTICAL PROCEDURES

The DNA analytical procedures used by the Virginia Division of Forensic Science, Forensic Biology Section are set forth in the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Procedure Manual, Section III, Fluorescent Detection PCR-Based STR DNA Protocol PowerPlex® 16 BIO System. Establishment of these procedures is guided by the Quality Manual, Section 4, Quality System Manuals and Control, and Section 17, Technical Procedures and Manuals.

1.8 CALIBRATION AND MAINTENANCE

Procedures for the calibration and maintenance of laboratory equipment are set forth in the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Procedure Manual, Section VI, Quality Assurance Program DNA Typing of Biological Materials. Establishment of these procedures is guided by the Quality Manual, Section 17, Technical Procedures and Manuals, Section 18, Supplies and Services, and Section 19, Equipment.

1.9 PROFICIENCY TESTING

The proficiency testing program for the Virginia Division of Forensic Science is referenced in Section 14.5 of the Quality Manual, Proficiency Testing, as well as Section 8 of the Quality Manual, Discrepancies and Corrective Actions.

1.10 CORRECTIVE ACTION

The procedure for corrective action is set forth in the Quality Manual, Section 8, Discrepancies and Corrective Actions.

1.11 REPORTS

The procedure for generating a Certificate of Analysis is addressed in the Quality Manual, Section 12, Reporting Results.

The procedure for the preparation, storage and disposition of case file records is addressed in the Quality Manual, Section 13, Case Files and File Administration.

The procedure for the expungement of records is addressed in the Quality Manual, Section 13.11, Expungement of Records.

1.12 REVIEW

The procedure for the peer review of case files is addressed in the Quality Manual, Section 14, Monitoring Results. To aid the Forensic Biology Section examiner during the review of the documentation found in the case file, the "Guide for Review of DNA Data" form found at the end of this chapter is used as a guide.

The procedure for the monitoring of the testimony of casework examiners is addressed in the Quality Manual, Section 14.4, Testimony Monitoring.

1.13 SAFETY

The policies and procedures for safety in the laboratory are addressed in the Division of Forensic Science Safety Manual.

1.14 AUDITS

The procedure for audits of the Virginia Division of Forensic Science is addressed in the Quality Manual, Section 10, Audits

A FBI Quality Assurance Audit of the Virginia Division of Forensic Science, Forensic Biology Section is conducted by an external agency at a minimum of every other year.

The official record and response to prior audits is maintained by the Virginia Division of Forensic Science Quality Assurance Coordinator in the Division's headquarters laboratory.

Guide for Review of DNA Data

Extraction worksheet
- Samples extracted from low to hi
- Knowns extracted separately from unknowns
- Appropriate reagent blanks used
- Extraction method specified

BioMek worksheet
- Lot #s recorded
- Samples & controls in proper location
- Plate control results documented, if data not included
- Operator actions initialed

AluQuant worksheet
- Operator actions initialed
- Calculated quantitations accurate
- Extrapolated values recorded for >4ng/ul samples
- Proper documentation present if STD curve adjusted
- Lot #s / Expiration dates recorded

Reagent/Amplification worksheet
- Lot #'s & expiration dates recorded
- Dilution/Amplification date recorded
- TC # & QC date recorded

Product gel/dilutions worksheet
- Lot #s recorded
- Interpretation results recorded
- Photograph/scan present and appropriately labeled
- Loading volume appropriate, if recorded
- Dilutions recorded, if not documented elsewhere

Gel Data worksheet
- Lot #s recorded
- Gel prep and run parameters
- Proper controls
- Gel loaded in accordance with protocol
- Sizing lanes designed, if applicable

Scanned images
- Scanning parameters printed, if possible
- Gel # documented

Final images
- Scanning parameters printed, if possible
- Gel # documented
- Lanes labeled
- BT bands addressed, if not done so in STaRCall
- Controls evaluated, proper action taken if expected values not obtained

Look-up tables
- Gel # documented
- bp values accurate
- Microvariant documented, if appropriate

STaRCall worksheets
- Gel # documented
- Lane designations accurate
- BT, ART, ??, and ST designations accurate
- Out of range values addressed including loci

Landscape worksheet
- Gel # documented
- Controls evaluated, proper action taken if expected values not obtained
- Changes match STaRCall
- INC loci on STaRCall addressed on landscape
- Verified against gel image, including intensity differences
- Differences in calls between sizers addressed

2nd sizer look-up tables, STaRCall, Landscape
- Gel # documented
- Consistent with examiner data
- Landscape verified by examiner

CODIS search result printouts
- Staff index search conducted, if appropriate
- Local and state search sheets included, if appropriate
- Proper indices searched
- Matches properly evaluated and documented
- Appropriate allele values used

Specimen detail report printouts
- All appropriate samples entered into CODIS
- Appropriate specimen nomenclature used
- Appropriate specimen category assigned
- Source ID appropriately chosen, if applicable
- Correct alleles entered for specimen
- Reported NDIS suitability consistent with data entry

Statistics
- Appropriate calculation used
- For LR, appropriate assumptions made
- Correct allele entered
- Sample description/identification listed
- Reported value listed on printout

♦END